

Enclosure No:	1/AWMSG/0523
Agenda Item No:	1 – Minutes of previous meeting
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All Wales Medicines Strategy Group (AWMSG)

**Draft minutes of the AWMSG meeting held
at 09.30 am on Wednesday 19th April 2023 at
The All Nations Centre, Sachville Avenue, Cardiff, CF14 3NY**

Voting members present:			Did not participate in agenda item:
1.	Prof Iolo Doull	Chairman	
2.	Dr Catrin Plumpton	Health Economist	
3.	Mr Tommy Price	ABPI (Wales)	4
4.	Mrs Claire James	Lay Representative	
5.	Mrs Pam James	Lay Representative	
6.	Mr Dylan Jones	Community Pharmacist	
7.	Ms Alison Hughes	Managed Sector Pharmacist	
8.	Mr Stuart Rees	Managed Sector Pharmacist	
9.	Mrs Katherine White	Senior Nurse	
10.	Mr Karl Jackson	Other healthcare professions eligible to prescribe	
11.	Dr Alison Thomas	Clinical Pharmacologist	
12.	Dr Manjeet Singh	Hospital Consultant	

Welsh Government:
Mr Andrew Evans

AWTTC staff:

Mr Trevor Brooking, Administration Manager
Mr Richard Boldero, Senior Pharmacist
Prof James Coulson, NMG Chairman
Mr Thomas Curran, Senior Scientist
Dr Paul Deslandes, Senior Pharmacist
Dr Clare Elliott, Senior Scientist
Mr David Haines, Medical Writer
Ms Karen Jones, Senior Pharmacist
Mrs Ruth Lang, Senior Liaison Manager
Mr Anthony Williams, Interim Programme Director
Mrs Gail Woodland, Senior Pharmacist
Mrs Claire Thomas, Senior Pharmacist

List of abbreviations:

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
ATMP	Advanced Therapy Medicinal Product
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BMA	British Medical Association
CAPIG	Clinical and Patient Involvement Group
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DHCW	Digital Health and Care Wales
DoH	Department of Health
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Board
HEIW	Health Education and Improvement Wales
HST	Highly Specialised Technology
HTA	Health Technology Assessment
ILAP	Innovative Licensing and Access Pathway
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
M&TC	Medicines & Therapeutics Committee
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NPI	National Prescribing Indicator
OWMAG	One Wales Medicines Assessment Group
PAMS	Patient Access to Medicines Service
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
QAIF	Quality Assurance and Improvement Framework
RCGP	Royal College of General Practitioners

SABA	Short-acting beta agonist
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
SPIRA	Server for Prescribing Information Reporting and Analysis
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

1. **Welcome and introduction**

The Chair opened the meeting, welcomed members and observers, and explained the meeting protocol.

2. **Apologies:**

Dr Jeremy Black, GP with prescribing lead role
 Dr Helen Fardy, Welsh Health Specialised Services Commission
 Prof Dyfrig Hughes, Health Economist
 Mr James Leaves, Director of Finance
 Dr Sian Lewis, Welsh Health Specialised Services Commission
 Mr Hywel Pullen, Director of Finance
 Dr Richard Skone, Medical Director
 Prof Stephen Monaghan, Consultant in Public Health Medicine

3. **Declarations of interest:**

The Chair invited declarations of interest. Mr Tommy Price declared an interest in agenda item 8: One Wales decision – rituximab for the treatment of myasthenia gravis in adults. The Chair confirmed that Mr Price would not participate in this agenda item.

4. **Minutes of previous meeting**

The draft minutes of the previous meeting held on 7 March 2023 were checked for accuracy and approved. There were no matters arising.

5. **Appraisal 1: Full Submission (WPAS)**

Levodopa/carbidopa/entacapone (Lecigon®) for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results

Submission by Britannia Pharmaceuticals. The Chair welcomed the company delegates and confirmed they would be invited to comment and respond to questions.

The Chair invited members to declare any interests in either the applicant company or the comparator medicine if they had not already done so. No interests were declared.

The Chair opened the appraisal session and confirmed that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation will not impact on the clinical freedom of the prescriber. A positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on Health Boards to fund accordingly. AWMSG advice is interim to NICE guidance, should this be subsequently published.

The Chair invited the appraisal lead, Ms Karen Jones, to give an overview of the submission.

Prof James Coulson summarised the discussion held at the NMG meeting and confirmed the recommendation to AWMSG that levodopa-carbidopa-entacapone (Lecigon[®]) is recommended as an option for restricted use within NHS Wales for indication outlined by Ms Jones.

Prof Coulson explained that NMG had acknowledged the uncertainty in the evidence presented. NMG noted that the use of a CMA did not capture any differences in patient preference and wider health benefits. NMG considered that for a plausible scenario that would reflect clinical practice in Wales in which entacapone or opicapone would be used in combination with Duodopa[®], that Lecigon[®] was unlikely to be significantly different in terms of cost-effectiveness. Prof Coulson confirmed that AWMSG's policy for appraising a medicine for a rare disease had been applied and the degree of severity of the disease in terms of survival and quality of life of the patient and carer(s) was taken into consideration.

Ms Jones relayed the views of clinical experts, who overall supported Lecigon[®] as a potentially useful option.

The Chair opened discussion and invited comments relating to clinical effectiveness. It was confirmed that study presented was not designed to capture clinical and safety outcomes, only pharmacokinetic evidence.

Dr Catrin Plumpton provided an overview of the case for cost-effectiveness and discussed the key considerations identified in the submission as outlined in the ASAR.

It was confirmed that the comparator medicine had an associated confidential patient access scheme. The company delegates were asked to leave the meeting so that commercial confidentiality could be maintained. Members considered the budget impact estimate to be reasonable. The company delegates returned for the remainder of the appraisal.

The lay member summarised the views and opinions from the patient perspective and reiterated that advanced Parkinson's has a severe impact on the patient, their families and carers, and that there are few treatment options in the late stages of this condition.

The Chair asked the company delegates if they wished to comment. The delegates emphasized that Lecigon[®] uses a combination of medicines

already in use by clinicians, and highlighted the potential benefits associated with the new pump system used to administer Lecigon®. The company acknowledged the uncertainty with some of the clinical and cost-effectiveness evidence. They thanked AWMSG members and confirmed that the process had been fair and all the issues had been adequately addressed.

The Chair informed the group that AWMSG's recommendation would be forwarded by email to the company after the meeting and a notice uploaded to the website. He confirmed that the recommendation would be forwarded to Welsh Government for ratification unless the company requests a review within ten working days of the meeting.

The following recommendation was subsequently confirmed:

Levodopa-carbidopa-entacapone (Lecigon®) is recommended as an option for restricted use within NHS Wales.

Levodopa-carbidopa-entacapone (Lecigon®) is licensed for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results.

Levodopa-carbidopa-entacapone (Lecigon®) is restricted within the licensed indication for patients who are not eligible for deep brain stimulation.

Levodopa-carbidopa-entacapone (Lecigon®) is not recommended for use within NHS Wales outside of this subpopulation.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

6. Chairman's report (verbal update)

The Chair announced that Mrs Mandy James, AWMSG's Senior Nurse representative had retired in March. Mrs James was thanked for her loyal and dedicated service over eight years and wished a happy retirement. Kathy White, Specialist Medicines Management Nurse from BCUHB has agreed to step into the role, with Susan Newport as the alternate member.

Members were informed the AWMSG Constitution, reviewed and updated in March to include a Chief Pharmacist representative, has been forwarded to Welsh Government for approval.

The Chair announced the upcoming Medicines Safety Day on 19th June, marking 40 years of the Yellow Card Centre Wales, and confirmed that members will be invited to this event.

The Chair provided details of the PAPIG meeting on Thursday 20th April, and confirmed an online therapeutics educational session will be run in collaboration with the RCGP on the evening of 20th April. Members were given feedback on the Learning at Lunch Therapeutics Update session facilitated by AWTTTC on the 30th March.

Members were asked to remain at the close of the meeting for a short workshop to inform the development of a new medicines strategy.

7. One Wales Policy update

Mrs Gail Woodland highlighted recent changes to the One Wales Medicines process and explained that the recommendations of OWMAG will in future be presented to AWMSG for endorsement before being submitted to Welsh Government for ratification. AWMSG members endorsed the process changes.

8. One Wales decision – rituximab for the treatment of myasthenia gravis in adults

Dr Clare Elliott provided members with an overview of the One Wales recommendation for rituximab in myasthenia gravis. It was explained that this recommendation was the first One Wales recommendation to come to AWMSG after the policy update. The Chair explained that members had been asked to raise any queries before the meeting, but opportunity still remained to ask questions or comment. No discussion points were raised. The Chair confirmed AWMSG's endorsement of the recommendation.

9. Opioids in palliative care – A patient information guide

Ms Karen Jones and Dr Paul Deslandes gave an overview of recent updates to the patient information guide, which was brought to AWMSG members for information. A comment was made that the length of the document might make it unmanageable. A suggestion was made to change the focus from Velindre to the whole of Wales. It was confirmed that further changes to the resource, including more accessible formats, would form the basis of a new project proposal from the authors.

10. Primary care antimicrobial guidelines

Mr Richard Boldero provided an update on changes to the Primary Care antimicrobial guidelines, for information. There were no issues of note.

11. Understanding licensed medicines

Dr Paul Deslandes and Dr Efi Mantzourani gave members an overview of the enclosure entitled 'Understanding Unlicensed Medicines' and asked for the endorsement of AWMSG. It was confirmed that Welsh translations of the accompanying Patient Information Leaflet would follow. The Chair confirmed AWMSG's endorsement.

12. Mental health medicines in older adults: Adverse Drug Reaction (ADRe) Profile to check patients for signs and symptoms of adverse effects

Dr Paul Deslandes presented an overview of the enclosure - Mental Health medicines in older adult's toolkit - outlining its aims and current use in practice.

There was discussion over the time it would take clinicians to use this toolkit in practice. It was questioned whether this was realistic and if there was any tangible benefit to patients. There was some concern amongst members that use of this toolkit may distract from the use of the Yellow Card system for

reporting ADR's.

The Chair confirmed AWMSG's acknowledge of the toolkit and asked AWTTC to make it clear on the website that this was not a mandated endorsement and the reporting of suspected reactions to medicines should be via the Yellow Card Scheme.

13. Sodium Valproate website hub (verbal update)

Mrs Claire Thomas updated members on the development of a hub, to be hosted on the AWTTC website, containing resources related to the safer prescribing of sodium valproate. Resources for healthcare professionals and patients have been developed based on the recommendations of the Welsh Government sodium valproate task force. The hub will be updated over time as more resources are made available, and will be launched in the coming weeks.

14. Draft minutes of AWPAG Meeting held 15th March 2023

Mrs Claire Thomas provided an overview of the AWPAG meeting held on the 15th March. A query was raised concerning a paper discussed at AWPAG regarding use of antipsychotics in dementia. It was noted that the paper presented was a first draft, with the authors in the process of updating the document based on feedback from AWPAG members. The member was encouraged to submit any comments on the document when it reaches the stage of open consultation.

15. Any other business

There was no other business.

The Chair confirmed the date of the next meeting on Tuesday 16th May 2023 in Cardiff